REMARKS

The Office Action of February 23, 2005 presents the examination of claims 6-13. The present paper amends claims 6-9, and cancels claims 12-13. The amendment to claim 9 is merely of a minor editorial nature. Claims 7 and 8 are amended to correct their dependency. The amendment to claim 6 is explained below.

Information Disclosure Citation

The Examiner has not provided Applicant with an initialed copy of the PTO-1449 form filed with the Information Disclosure Statement filed April 1, 2004. The Examiner is respectfully requested to send an initialed copy that form PTO-1449 with the next Office communication.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 6-12 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description of the invention. In particular, the Examiner asserts that the specification fails to describe producing an antiidiotypic antiembryonic antiserum using animals other than a rat. The Examiner's assertion that, because the immune response to a population of antigens is different from species to species, and because the determinants of antigenicity vary from protein to protein, the specification fails to adequately describe the invention in broad terms. The Examiner then concludes, in a confusing manner, that, "Therefore there is no nexus between the activated spleen cells in a rat produced by immunization of said rat with a rat embryo from the same genetic line."

Applicants disagree that the specification fails to describe the instant invention sufficiently to establish that the inventors are in possession of the invention as claimed. The Examiner fails to meet her burden of explaining why the generic teachings of the invention are not appropriate. The Examiner fails to explain why the working example

of the invention is not broadly applicable. Applicants submit that merely because it is unpredictable what particular epitopes will turn out to be represented in an antiidiotypic antiembryonic antiserum made in the manner described in the specification, it is not unpredictable that an antiserum representing epitopes specific for embryonic proteins can be raised by that method.

In any event, to advance prosecution of the application, Applicants have at this time amended the claims to recite that the antiidiotypic antiserum is raised in rats. This conforms the claims to the teachings of the working example and therefore it must be acknowledged that the presently claimed invention is adequately described in the specification.

Claims 6-13 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement by the specification. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner makes two arguments, both of which are rendered moot by the amendment to the claims above. First, the Examiner asserts that the specification does not enable the making of the claimed antiidiotypic antiembryonic antiserum in the manner claimed. The present claims recite that a rat is immunized, etc. and thus the instant claims are conformed to the working example. The Examiner has not provided any reasoning or evidence to doubt the veracity of the working example and therefore this basis for the rejection is overcome.

The Examiner does state that, "The antiidiotypic antiembryonic antiserum would be expected to bind to antiserum evoked from the fetal antigens not recognized as 'self' on the first animal, but said antiidiotypic antiserum would not be expected to bind to 'non self' fetal antigens." It is not at all clear what the Examiner is trying to say by this

or why it is relevant to the question of enablement. The specification rather clearly states at page 3, lines 14-16, that the resulting antiserum binds to the idiotype of a T-cell receptor for tumor antigen. That is, the antiserum specifically recognizes T-cells that recognize a tumor antigen expressed by embryonic tissues but not present on normal tissues of an adult.

The Examiner's arguments that the specification fails to enable step v) of the process because the particular organs to be used are not disclosed is entirely without merit. At page 2, lines 3-7, the specification describes heterospecific antigens, and that these exist in normal tissues in addition to being expressed in tumors. The specification indicates that kidney tissue and liver should be used as agents to remove antibodies against these heterospecific antigens. Furthermore, the artisan of ordinary skill understands that the purpose of adsorbing the intial antiserum with whole organs (or pieces thereof) is to remove antibodies that bind to antigens expressed by normal tissues. Thus, the performing of this step is not beyond the skill of one of ordinary skill in the art of producing an antiserum.

Finally, the Examiner argues that the specification fails to enable a diagnostic test relying upon agglutination of the antiidiotypic antiembryonic antiserum with a blood sample from a "subject", as it would be necessary to experimentally determine the parameter α that provides a diagnostic criterion for each pairing of kind of animal in which the antiserum is raised and kind of animal that is the "subject". Applicants submit that such experimentation is not undue. However, again to advance prosecution, Applicants submit that the amendment to the claims to conform them to the present working example obviates this basis for the rejection.

For all of the above reasons, the instant rejection of claims 6-13 under 35 U.S.C. § 112, first paragraph, for lack of enablement, should be withdrawn.

Applicants submit that the present application well-describes and claims patentable subject matter. The favorable action of withdrawal of all of the standing rejections and passage of the application to issue are respectfully requested.

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Respectfully submitted,

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